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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,743	05/09/2001	James Nolan	00-388-A	4067

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Kevin E. Noonan  
McDonnell Boehnen Hulbert & Berghoff  
32nd Floor  
300 S. Wacker Drive  
Chicago, IL 60606

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/851,743	NOLAN ET AL.
	Examiner	Art Unit
	Shahnam Sharareh	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 11/4/2002, 5/9/2001.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) 8-12 and 20-24 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-7, 13-19 and 25-34 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8-12, 20-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

This application contains claim 8-12, 20-24 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Priority***

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112, 1<sup>st</sup> paragraph for claims 1-7, 13-19, 25-34 of this application. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 13-19, 25-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "more rapidly," "more completely," or "less painfully" in claims 1 and 13 is a relative term which renders the claim indefinite. These terms are not defined by the claim and are in general subjectively measured among individuals. Further, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 5, 13, 27, 32 recite the limitation "the human." There is insufficient antecedent basis for this limitation in the claim.

Step (c) of the claims 1 and 13 is confusing. It is not clear what is meant by "comparing wound healing in the presence of the compound to wound healing in the presence of the compound." This limitation appears vague as it is not clear what is exactly being compared to which compound?

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-4,6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong US Patent 6,001,357.

The instant claims appear to be directed to methods of identifying a compound useful for treating skin wounds comprising producing a skin wound on animals, allowing the skin to heal in the absence of a test compound, and in the presence of the test compound, comparing the duration of wound healing in the absence and in the presence of the test compound, identifying those compounds that qualitatively perform better in said comparing step.

Wong discloses animal models of assessing the efficacy of a drug in treating skin wound. (see col 6, lines 5-67). Essentially Wong first creates a wound site. Then, after establishing the wound healing parameters, he creates a control and therapeutic group of animals and applies the test chemicals accordingly. Wong finally compares the performance of test chemicals on treating skin wounds (col, lines 25-65; col 8, lines 15-60; col 10, lines 15-67; col 11-12). Accordingly, Wong anticipates the limitations of the instant claims.

Claims 1, 3-4,6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al US Patent 6,232,341.

Chen discloses methods of assessing the efficacy of topical therapeutic preparation in treating skin wound comprising creating a wound, applying the drug of interest randomly among animals, comparing the rate of healing and assessing the efficacy of the drug (see example 3, col 5-8). Thus, Chen anticipates the limitations of the instant claims.

***Claim R j cti ns - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 13-19, 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al US Patent 5,232,341 in view of Jones et al Wo 99/50268 ('268) and Spence US Patent 4,226,232.

The teachings of Chen is described above. Chen does not teach the employment of his methodology in assessing aldose reductase inhibitors in treating skin wounds associated with diabetic nephropathy.

Jones teaches the use of aldose reductase inhibitors in treating diabetic nephropathy. (see page 81, lines 3-23). Specifically, Jones teaches that aldose reductase inhibitors can be used to normalize or reduce sorbital accumulation in the sciatic nerve of streptozotocin induced diabetic rats as taught by Mylari et al.

Spence is solely used to show the general knowledge in the art in comparatively assessing agents of choice in treating skin wounds (see col 5, lines 1-47).

Accordingly, even though Chen does not explicitly use aldose reductase inhibitors as the control agent in his methodology, it would have been obvious to one of ordinary skill in the art at the time of invention, to use an aldose reductase inhibitor for comparative assessment of therapeutic efficacy of other agents, because as suggested by WO '268, the ordinary artisan would have had a reasonable expectation in observing positive results from such agent in treating diabetic neuropathy and thus it would have been well within purview of an ordinary artisan in the field of pharmacology to ascertain the relative efficacy of other therapeutic agents in relation to an aldose reductase inhibitor.

Further, as described by Spence, comparatively determining the pharmacological efficacy of a therapeutic agent in treating skin wounds is routinely practice by ordinary skilled in the art (see col 5, lines 10-50), thus, absence of unexpected results, assessing

therapeutic efficacy of drugs in treating skin wound would require the same method steps for any skin etiology including those caused by diabetes.

***Conclusion***

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

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*Russell Travers*  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200